Jondavid Klipp, Editor, labreporter@aol.com

Volume 11, No. 6 June 2016

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

QUEST TO MANAGE INPATIENT LABS AT SIX HEALTHONE HOSPITALS IN DENVER

Under a new agreement, which does not involve the acquisition of any physical assets, Quest Diagnostics will manage inpatient clinical lab operations for six HealthONE hospitals with a combined 1,600 staffed beds. HealthONE, owned by the national for-profit hospital chain HCA, is the largest healthcare system in Denver with 10,000 employees and 3,000 affiliated physicians.

When Quest manages a hospital's inpatient lab, it moves 20% to 30% of tests to its own facilities, which can trim 10% to 20% of a hospital's lab costs, according to Jon Cohen, MD, Senior Vice President at Quest. The deal displaces LabCorp which has a longstanding relationship with HCA and had been the primary reference lab for HealthONE. *Continued on page 2.*

DARK SUES EX-EMPLOYEES OVER WEBINARS

The Dark Intelligence Group (TDIG-Spicewood, TX), publisher of *The Dark Report*, has filed suit against Justin Clark and Leslie Davidson alleging breaches of contract, misappropriation of proprietary information, and tortious interferences with current contractual relationships. The case involves a business ("PathologyWebinars.com") formed by Clark and Davidson to sell webinars to clinical laboratories and pathologists. TDIG is seeking an injunction to stop Clark and Davidson from offering webinars in the clinical laboratory and anatomic pathology space. The lawsuit (case no. D-1-GN-16-001965) was filed on May 6 in the District Court of Travis County, Texas. *Continued on page 5.*

UNITED SUES 5 DRUG TESTING FIRMS FOR $50 MILLION KICKBACK SCHEME

UnitedHealthcare is suing five related toxicology lab companies (Sky Toxicology, Frontier Toxicology, Hill Country Toxicology, Eclipse Toxicology and Axis Diagnostics), alleging they defrauded UHC and its members out of more than $50 million through a kickback scheme for urinalysis tests. The lawsuit, filed in Florida federal court (case no. 9:16-cv-80649-RLR), also named William "Wade" White, MD (the CEO at each lab defendant) as well as two other lab executives, Lance Hupfeld and Bradley West. *Continued on page 7.*

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QUEST TO MANAGE INPATIENT LABS AT HEALTHONE (*cont'd from page 1*)

Under the agreement, 14 lab management positions will transfer to Quest, while the remaining 300 hospital lab employees will remain with HealthONE. The agreement covers inpatient clinical lab tests only. Quest is not purchasing any outreach business.

Anatomic pathology services, including Pap tests, will remain under the management of each hospital's pathology department, which will also maintain the Laboratory Medical Director responsibilities at each of the six hospitals.

Quest will manage the inpatient labs at the following Denver-area HealthONE hospitals:

Hospital (location)	*Staffed Beds*	*Patient Days*
Swedish Medical Center (Englewood, CO)	342	94,215
The Medical Center of Aurora (Aurora, CO)	315	71,890
Sky Ridge Medical Center (Lone Tree, CO)	269	54,934
Presbyterian/St. Luke's Medical Center (Denver, CO)	244	78,326
Rose Medical Center (Denver, CO)	244	51,980
North Suburban Medical Center (Thornton, CO)	127	27,774

Source: American Hospital Directory 2015

HealthONE's existing reference work (now handled by LabCorp) will be redirected into Quest facilities. Tier 2 non-urgent test volumes now performed at HealthONE hospital labs will also be moved to Quest facilities, primarily Quest's full-service regional labs in Denver and Lenexa, Kansas. Test volumes are expected to be transitioned by the end of this year. Tests moved to Quest facilities will benefit from the company's purchasing economies of scale for reagents, supplies and equipment.

Despite the significant test volume shifts, HealthONE is not expected to make any layoffs, according to a spokeswoman from HealthONE.

Among the 14 lab management positions that are expected to be directly employed by Quest are the administrative clinical lab directors at each of the hospitals as well as a regional hospital lab director who will supervise all six hospital labs.

Based in Nashville, HCA (Hospital Corp. of America) is the largest for-profit hospital chain in the nation. It manages 168 hospitals with a total 43,000 beds and has annual revenue of more than $40 billion. A Quest spokesman would not comment on whether or not the HealthONE partnership could lead to other similar partnerships with more HCA hospitals.

HealthONE represents the seventh professional lab services agreement that Quest has made with a hospital system in the past five years. Most recently, Quest completed an inpatient lab management deal with Barnabas Health in northern New Jersey (see *LE*, December 2015, p. 1).

During an April 21 conference call with analysts, Quest CEO Steve Rusckowski said this about the Barnabas deal:

> During the first quarter, we began to manage Barnabas Health's hospital laboratory operations under a new professional lab services or PLS agreement. Tradition-

> ally, these agreements, which represent organic revenue growth, cover management of inpatient and outpatient testing for the hospitals and do not require the same level of services such as phlebotomy and logistics. Here we bill and collect directly from the hospital. Due to the nature of this business, Barnabas will pressure our revenue per acquisition as we move through the year. In addition, keep in mind that PLS margins for any given relationship will improve over time as we implement our processes and protocols.

Meanwhile, Rusckowski said that Quest also continues to look for straight-out purchases of hospital lab outreach businesses. On the conference call, Quest's Chief Financial Officer, Mark Guinan, confirmed that Quest paid $135 million to Hartford HealthCare for its lab outreach business (Clinical Laboratory Partners) in March (see *LE*, March 2016, p. 4). In terms of the multiple of EBITDA (earnings before interest, taxes, depreciation and amortization) that Quest typically pays for hospital lab outreach business, Guinan said:

> There is really no multiple that makes sense in terms of the seller's revenue and EBITDA because the business in our hands is completely different. So the revenue tends to be lower as we move the reimbursement to our negotiated rates, but obviously in all cases when we do an acquisition, the EBITDA and the earnings are much better than what the seller had….On a pro-forma basis, if you saw our models, you would see that the multiple that we are paying on an EBITDA basis is not above our overall market multiple [currently approximately 7.3x], so it would be in the ballpark or lower. So you can feel good that we're not going to be buying companies or assets or businesses at a significantly high premium.

PROPOSED PHYSICIAN FEE SCHEDULE DUE OUT IN JULY

Medicare's proposed Physician Fee Schedule for 2017 is expected to be published in July. Last year, CMS identified the following eight pathology services (see table) as potentially misvalued and subject for review. Altogether, the eight codes represent $220 million in annual Part B allowed charges. Any payment rate changes as a result of review would be effective as early as January 1, 2017.

The biggest Medicare rate changes could be coming to two key flow cytometry codes (CPT 88185 and 88189). Any potential rate changes would have a big effect on Genoptix (Carlsbad, CA), which is owned by drug-maker Novartis and is the top flow cytometry lab in the nation. Its lab in southern California received $17 million in allowed Part B payments for CPT 88185 and 88189 in 2014, according to the latest available data from CMS.

Pathology Codes Identified as Potentially Misvalued

Code	Description	Medicare Part B Global Rate, 2016	National Part B Allowed Charges*
10022	FNA with image guidance	$142.95	$20,240,208
36516	Apheresis selective	2,113.49	2,734,407
38221	Bone marrow biopsy	170.18	13,935,841
88185	Flow cytometry/TC add-on	46.22	104,896,066
88189	Flow cytometry/read 16 & > markers	114.29	20,789,757
88321	Microslide consultation	103.54	16,842,279
88360	Tumor immunohistochem/manual	121.81	26,047,511
88361	Tumor immunohistochem/computer	149.40	14,257,985

Source: *Laboratory Economics* from CMS

Bio-Reference Labs (Elmwood Park, NJ), now owned by Opko Health, received $12.1 million in Part B payments for CPT 88185 and 88189 in 2014. And Florida Cancer Specialists, the largest oncology group in Florida, received $6.2 million.

TOP 25 FLOW CYTOMETRY LABS BY PART B PAYMENTS, 2014

LABORATORY NAME	LOCATION	TOTAL PART B CLAIMS 88185 & 88189	TOTAL ALLOWED PART B PAYMENT 88185 & 88189
GENOPTIX, INC.	CARLSBAD, CA	281,359	$17,043,032
OPKO/BIO-REFERENCE LABS	ELMWOOD PARK, NJ	182,904	12,133,287
FLORIDA CANCER SPECIALISTS	FORT MYERS, FL	106,438	6,244,933
LABCORP	NEW YORK, NY	75,722	5,063,895
MIRACA LIFE SCIENCES	IRVING, TX	87,351	4,962,755
LABCORP/ACCUPATH DIAGNOSTICS	BRENTWOOD, TN	91,707	4,713,832
CLARIENT DIAGNOSTIC SERVICES	ALISO VIEJO, CA	46,105	3,217,880
LABCORP	RES. TRIANGLE PARK, NC	52,240	2,522,288
QUEST NICHOLS INSTITUTE EAST	CHANTILLY, VA	35,581	2,374,160
QUEST NICHOLS INSTITUTE WEST	SAN JUAN CAPISTRANO, CA	30,841	1,930,407
HEMATOGENIX LAB SERVICES	TINLEY PARK, IL	32,402	1,922,852
NEOGENOMICS LABORATORIES	FORT MYERS, FL	30,059	1,771,001
CYTOMETRY SPECIALISTS, INC.	ALPHARETTA, GA	27,011	1,604,837
CLEARPOINT DIAGNOSTIC LABS	LEWISVILLE, TX	32,413	1,594,071
HISTOPATHOLOGY SERVICES LLC.	SUFFERN, NY	22,209	1,465,544
LABCORP/ACCUPATH DIAGNOSTICS	PHOENIX, AZ	24,226	1,307,317
AMERIPATH NEW YORK	SHELTON, CT	20,383	1,278,060
PATHOLOGISTS BIOMEDICAL LABS	LEWISVILLE, TX	21,720	1,254,814
AMERIPATH TEXAS	IRVING, TX	21,425	1,237,902
NEOGENOMICS LABORATORIES	IRVINE, CA	17,472	1,192,802
SIPARADIGM LLC	ORADELL, NJ	16,680	1,121,428
APPLIED DIAGNOSTICS	HOUSTON, TX	16,794	951,476
QUEST DIAGNOSTICS	HORSHAM, PA	13,609	824,253
LABCORP/DIANON SYSTEMS	SHELTON, CT	11,966	750,791
SONIC HEALTHCARE/CBLPATH	RYE BROOK, NY	11,023	742,816

Source: *Laboratory Economics* from CMS (data for calendar-year 2014)

DARK SUES FORMER EMPLOYEES (*cont'd from page 1*)
According to the lawsuit, Justin Clark was employed as TDIG's office manager beginning in June 2008. His responsibilities included participating in TDIG's webinars and audio conferences. "Although Clark did not produce or market those programs, or choose their topics or speakers, Clark did manage some aspects of the process of scheduling, preparing, conducting, and wrapping up events. He also served as the 'moderator' of some of the webinars," according to the suit.

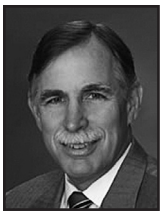
The lawsuit states that TDIG hired Leslie Davidson (d/b/a Davidson Direct) as a consultant in the winter of 2008 to assist in the production and promotion of some of its webinars and audio conference programs.

According to the lawsuit, TDIG "suspended its webinar/audio conference program in April 2012 due to its poor performance… At that time, TDIG terminated its relationship with Davidson."

The lawsuit further states that TDIG terminated its employment relationship with Clark in May 2012. In connection with his severance agreement, Clark agreed to, among other things, "not use for his own benefit and/or sell, distribute, or disclose to any person or entity any proprietary information, trade secrets or work product owned or developed by [TDIG], including but not limited to vendor lists, business models, and plans." As part of the severance agreement, TDIG paid Clark $3,500 plus accrued vacation time pay and he agreed not to work for any competitor for a period of nine months.

The lawsuit claims that Clark breached this agreement with TDIG, and that Davidson violated her fiduciary duty to TDIG, by collaborating to create and market webinars for clinical labs and pathologists in direct competition with TDIG. In the lawsuit, TDIG claims that Clark and Davidson wrongfully appropriated TDIG's confidential customer lists to market webinars "deceptively similar" to TDIG's through their PathologyWebinars.com website. "Defendants have created PathologyWebinars display advertisements, marketing information in the trade dress used by TDIG to look as if it is produced by TDIG, when in fact it is not," alleges TDIG.

Furthermore, the lawsuit alleges that Clark, acting through surrogates, illegally and improperly used TDIG's proprietary Executive War College discussion group on LinkedIn.com to send emails to several thousand TDIG customers advertising a webinar produced by Clark and Davidson.


Robert Michel

As mentioned earlier, TDIG is seeking an injunction to stop Clark and Davidson from offering webinars in the clinical laboratory and anatomic pathology space. As of publication time, Clark and Davidson had not yet filed a response to the lawsuit.

TDIG's President and owner, Robert Michel, declined to comment to *Laboratory Economics* on the case.

In an emailed statement to *Laboratory Economics*, Clark and Davidson said,
"The lawsuit has no merit. It is designed to inhibit fair competition that our company has generated in the laboratory and pathology space. While his suit mentions a temporary injunction, our understanding from his attorney is that there are no plans to pursue that request at this time. We believe there is enough demand from laboratories and pathologists for the type of information we provide to support multiple businesses in this market—including us, TDIG, and the other companies doing webinars in this space. In the meantime, Pathology Webinars, Inc. continues to provide webinars on important topics from experts in the field."

THIRD LAWSUIT TARGETS BOTH THERANOS AND WALGREENS

Lawsuits alleging consumer fraud are piling up for the embattled Theranos (Newark, CA). Most recently, Theranos was slapped with a third class action lawsuit (Case 5:16-cv-02891-NC) filed on May 30 in U.S. District Court in Northern California. Though similar to the first two suits, the latest suit goes one step further by naming Walgreens as a defendant.

The third suit was filed on behalf of a single Arizona resident with the initials R.G. who purchased a Theranos test at a Walgreens in Gilbert, Arizona, in September 2015. The suit alleges that Theranos used false advertising when it claimed to be using proprietary testing technology requiring only a fingerstick sample when, in fact, it was using venous blood samples and traditional lab equipment for most of its test menu (190 out of 205 tests offered).

Furthermore, the suit alleges that when Theranos did use its proprietary Edison testing technology, it did not work properly. As a result, patients may have "been subject to unnecessary or potentially harmful treatments, and/or been denied the opportunity to seek treatment for a treatable condition." It also alleges that Walgreens, which partnered with Theranos to offer tests at its drug stores in Arizona and California, endorsed Theranos' testing technology without ever verifying its accuracy.

Theranos Movie Planned

Believe it or not, actress Jennifer Lawrence is set to star as Elizabeth Holmes in a film about Theranos. The film will be produced by Adam McKay, who recently produced the The Big Short—about the housing market bubble. It will be interesting to see who delivers the best performance: Lawrence trying to portray Holmes, or Holmes herself trying to recover from her self-made debacle.

Plaintiffs in all three lawsuits seek class certification, restitution, an injunction and damages for false advertising, breach of contract, fraud, unfair business and unjust enrichment. All three suits still need to be certified by a judge and could potentially be rolled into one.

A Theranos spokesperson says the lawsuits are "without merit" and that "The company will vigorously defend itself against these claims."

Walgreens Kicks Theranos Out of Its Stores

In related news, Walgreens announced on June 12 that it is terminating its relationship with Theranos and closing operations at all 40 Theranos Wellness Centers at its stores in Arizona, effective immediately. This follows the company's decision in January to halt Theranos lab testing services at its Palo Alto, California, location, and means that Walgreens will no longer offer Theranos services at any of its stores.

"In light of the voiding of a number of test results, and as the Centers for Medicare and Medicaid Services (CMS) has rejected Theranos' plan of correction and considers sanctions, we have carefully considered our relationship with Theranos and believe it is in our customers' best interests to terminate our partnership," said Brad Fluegel, Walgreens Senior Vice President and Chief Health Care Commercial Market Development Officer.

Theranos says it will continue to do business in Arizona at five stand-alone patient service centers that it currently runs, apart from Walgreens stores. The company says it currently has five locations in Arizona and one in California, and plans to add more.

Holmes to Speak at AACC

Finally, the American Association of Clinical Chemistry (AACC) has announced that Theranos CEO Elizabeth Holmes will give a non-plenary presentation at its annual meeting on August 1 in Philadelphia. During the 90-minute presentation, Holmes is to present scientific and technical data describing Theranos' proprietary testing technology and answer questions from the audience. How-

ever, there will be no open microphones for attendees to ask un-vetted questions. Instead questions will be submitted to AACC moderators who will then select the "best questions" to ask Holmes.

In a letter to its members, AACC President Patricia Jones, PhD, said the session is not an endorsement of Theranos and the company has not provided any financial contribution to AACC.

To date, Theranos has not published any peer-reviewed studies detailing exactly how its proprietary testing technolology works. In a December 2014 article in *The New Yorker*, Holmes's description of the process was comically vague: "A chemistry is performed so that a chemical reaction occurs and generates a signal from the chemical interaction with the sample, which is translated into a result, which is then reviewed by certified laboratory personnel."

AURORA DIAGNOSTICS NAMES WALSH CHIEF MEDICAL OFFICER

Aurora Diagnostics (Palm Beach Gardens, FL) has promoted F. Michael Walsh, MD, to Chief Medical Officer. Dr. Walsh will continue to serve as chair of Aurora's Surgical Pathology Medical Advisory Committee. He joined Aurora Diagnostics in October 2015 when Aurora paid $6.5 million (plus $2.6 million in contingent notes) to acquire Laboratory Medicine of Greater Toledo, which Walsh founded.

Separately, Aurora reported that it paid a total of $7 million cash at closing and issued $1.5 million of contingent notes payable over three years for its recent acquisition of Pacific Pathology Associates (PPA-Salem, OR). PPA is a hospital-based pathology practice with eight pathologists serving five hospital contracts (see *LE*, April 2016, p. 9). Aurora says payments under the contingent notes will be paid annually, up to a maximum of $1.5 million, subject to the future financial performance of PPA and the retention of a key hospital contract.

Recent Acquisitions by Aurora Diagnostics

Date	Name	Cash Price	Contingent Notes
July 15, 2015	Brazos Valley Pathology and Trinity Pathology Assoc. (Texas)	$8.8M	$9.3M
Oct. 29, 2015	Laboratory Medicine of Greater Toledo (Toledo, OH)	$6.5M	$2.6M
March 31, 2016	Pacific Pathology Associates (Salem, OR)	$7.0M	$1.5M

Source: Aurora Diagnostics

UNITED SUES 5 DRUG TESTING FIRMS (*cont'd from page 1*)
The lawsuit alleges that the five toxicology labs and their executives used a three-pronged scheme that was uncovered by UHC's fraud unit which found that the lab defendants far exceeded their peers in both claims and payments per member (see related story on p. 8).

In the first part of the alleged scheme, referring drug addiction treatment centers and doctors were sold ownership stakes in the toxicology labs. These referrers were then paid monthly partnership distributions of tens of thousands of dollars that far exceeded the cost of their investments in the toxicology labs, according to the complaint. UHC says the defendants also encouraged and demanded referrers to order unnecessary and/or unauthorized urinalysis tests. In addition, the lawsuit claims that the defendants systematically waived UHC members' payment responsibilities.

UHC is seeking actual and consequential damages, treble damages, punitive and exemplary damages, reimbursement of legal costs, and injunctive relief.

This is the second time a private insurance company has sued Sky Toxicology. Last year, Cigna sued Sky alleging a $20 million civil fraud. The case was settled out of court for undisclosed terms.

DRUG TEST FIRMS AVERAGE 34 TESTS PER MEDICARE PATIENT

The top 20 drugs-of-abuse testing lab companies performed an average of 34 tests per Medicare patient they served in 2014, according to data analyzed by *Laboratory Economics* from the Medicare Part B program. On average, the 20 labs received $765 in Medicare payments for each Medicare patient they served in 2014.

Hill Country Toxicology, which is being sued by UHC, was the biggest outlier with an average of 70 CPT codes billed per Medicare patient served in 2014 and an average allowed Part B payment of $1,585 per patient.

At the low range was DrugScan Inc. (Horsham, PA), which billed an average of 16 CPT codes per Medicare patient served in 2014 and had an average allowed Part B payment of $368 per patient.

Top 20 Drugs-of-Abuse Testing Labs by Medicare Part B Payments, 2014

COMPANY	LOCATION	NUMBER OF PATIENTS	VOLUME SERVICES PERFORMED	AVG. SERVICES PER PATIENT	TOTAL ALLOWED MEDICARE PAY	AVG. PAID PER PATIENT
MILLENNIUM HEALTH	SAN DIEGO, CA	206,584	7,471,981	36	$170,143,962	$824
AMERITOX LTD.	GREENSBORO, NC	106,370	3,171,416	30	74,523,650	701
AEGIS SCIENCES CORP.	NASHVILLE, TN	78,623	2,826,271	36	59,034,905	751
PHYSICIANS CHOICE LAB	ROCK HILL, SC	37,114	1,815,662	49	42,622,224	1,148
AVUTOX LLC	ROCKY MOUNT, NC	12,304	714,367	58	17,293,025	1,405
CONFIRMATRIX LABORATORY	LAWRENCEVILLE, GA	15,860	835,205	53	16,473,960	1,039
CASTLE MEDICAL	SMYRNA, GA	17,140	817,506	48	16,420,754	958
ALERE TOXICOLOGY	AUSTIN, TX	36,390	530,631	15	13,771,765	378
DOMINION DIAGNOSTICS	N. KINGSTON, RI	22,781	611,959	27	13,728,310	603
PREMIERTOX	RUSSELL SPRINGS, KY	8,683	366,296	42	8,851,901	1,019
COMPASS LAB SERVICES	MEMPHIS, TN	10,979	420,757	38	8,625,345	786
AMERICAN INSTITUTE OF TOX	INDIANAPOLIS, IN	24,319	294,639	12	8,156,318	335
HILL COUNTRY TOXICOLOGY	SAN ANTONIO, TX	4,427	309,295	70	7,018,258	1,585
AMERICAN FORENSIC TOX	HUNTINGTON, NY	9,642	272,902	28	6,149,464	638
DRUGSCAN INC.	HORSHAM, PA	15,801	250,183	16	5,807,739	368
ROCKY MOUNTAIN TOX	DENVER, CO	8,789	248,179	28	5,784,192	658
TEXAS MEDICAL TOXI-COLOGY	HOUSTON, TX	4,222	231,982	55	5,721,814	1,355
ESSENTIAL TESTING LLC.	COLLINSVILLE, IL	10,243	295,763	29	5,534,267	540
CALLOWAY LABORATORIES	WOBURN, MA	11,507	198,517	17	5,381,508	468
REGIONAL TOXICOLOGY	TACOMA, WA	6,499	219,274	34	4,917,528	757
TOTALS & AVG., 20 LABS		648,277	21,902,785	34	$495,960,889	$765

Source: *Laboratory Economics* from Medicare Part B Provider Utilization Data for 2014

HIGHMARK TO BEGIN PRE-AUTHORIZATION FOR MOLECULAR TESTS

Beginning July 1, 2016, Highmark (Pittsburgh, PA), will require prior authorization for several molecular and genomic tests when performed in an outpatient setting. The insurer has contracted with eviCore's Lab Management Program to handle the prior authorization.

According to eviCore, its Lab Management Program uses evidence-based policies to ensure that genetic lab services provided to Highmark's members support clinically appropriate care and are medically necessary.

Procedures that will require prior authorization include the following:

- ❑ Molecular pathology tests (81161-81479)
- ❑ Multianalyte assays with algorithmic analysis (81500-81599, 0004M-0010M)
- ❑ Molecular infectious disease testing (87149-87912 and G0476)
- ❑ Molecular cytopathology procedures (88120-88121, 88182-88199)
- ❑ Cytogenetics (88230-88299)
- ❑ Molecular surgical pathology procedures (88341-88344, 88360-88361, 88364-88369, 88373-88377, 88380-88388)
- ❑ Other molecular codes (84999, 98240, 89240)
- ❑ Molecular HCPCS codes (S3800-S3890, G0452, G0464, G9143)

Highmark joins a number of other insurers who have turned to lab management programs to reduce what they see as unnecessary utilization, including Aetna, Cigna, Humana, UnitedHealthcare and most BlueCross plans. Because the cost of molecular and genomic testing is so high, insurers say they want to be sure such tests are absolutely necessary before a patient receives them.

Pre-authorization requests first go to a genetic counselor with eviCore; if the counselor denies the test, the request is automatically sent to a physician for review, explains Lon Castle, MD, chief of molecular genetics and personalized medicine at eviCore. "It's not about reducing expenses," Dr. Castle tells *Laboratory Economics*. "It's more about reducing the inappropriate use of tests. We're not looking to deny anyone from getting testing."

According to Castle, there are about 60,000 genetic testing products available in the market, with eight to 10 new ones being introduced every week.

"It's a challenge for physicians to keep up with all of the new tests," he says. "We try to help them figure out which tests are the right ones to order."

Leilyn Perri, a spokesperson for Highmark, tells *LE* that the insurer chose to partner with eviCore because genetic testing is so highly specialized and evolving. "The practice of using evidence-based guidelines in medical care results in safer treatments and outcomes," she says.

EviCore previously was known as CareCore National. In 2014, it merged with MedSolutions, a competitor. The firm has a staff of about 3,200, including about 1,000 healthcare professionals. According to Castle, its client health plans serve more than 90 million Americans in commercial, Medicare and Medicaid plans.

CIGNA EXPANDS GENETIC TESTING COUNSELING PROGRAM

Cigna is expanding its mandatory genetic counseling program to include additional tests as of July 15, 2016. The insurer began the counseling program in 2013 as a medically necessary requirement for patients undergoing genetic testing for hereditary breast and ovarian cancer (BRCA), colorectal cancer syndromes, and Long QT syndrome, a hereditary heart condition.

The program is now being expanded to include genetic counseling for four additional tests: Exome test, hereditary arrhythmias and cardiomyopathies, pediatric microarray test (excluding prenatal testing) and hereditary cancer syndromes. Counseling must be performed by a participating, independent board-certified genetic counselor or clinical geneticist prior to requesting precertification for the testing.

Jeffrey Hankoff, MD, chief medical officer, clinical performance and quality for Cigna, tells *Laboratory Economics* that the expansion is designed to help Cigna customers make informed health care decisions.

"The number of tests on the market has increased exponentially over the past several years," he says. "In many cases, the tests have no proven clinical value and can, in fact, cause harm. For example, a patient might get a false positive result, which can lead to more tests or even invasive medical procedures that are unnecessary and have their own risk factors. They may also get results that show they have a hereditary condition for which there's no known medical intervention—and that information could become a part of their medical record that will follow them for the rest of their lives. Our goal is to help the right people get the right test with the right information so they can make an informed decision that might be life-altering."

ASCO Opposes Expansion

The American Society of Clinical Oncology (ASCO) opposes the Cigna policy, saying that it introduces an unnecessary barrier to the appropriate use of genetic testing services and has the potential to negatively impact care provided to patients with cancer.

ASCO notes that 5% to 10% of cancers are attributable to a hereditary cancer predisposition syndrome. As research in clinical cancer genetics advances, offering hereditary cancer risk assessment has become an expectation in oncology practice, and many oncologists now routinely provide testing for high penetrance alleles (i.e., BRCA 1 and 2).

"The question of who should and should not be tested for inherited cancer susceptibility is of great significance for oncology providers and patients," says ASCO in a statement. "ASCO's updated genetic testing policy underscores the importance of pre- and post-test counseling for individuals offered genetic testing for cancer risk. Cigna's policy discounts the ability of appropriately trained oncology nurses and physicians to adhere to established guidelines and make proper recommendations for genetic counseling and testing, and it eliminates patients' choice in obtaining information from the provider they wish."

Dr. Hankoff responds that he would hope that oncologists and other physicians will see Cigna and its genetic counseling partner, InformedDNA, as allies who can provide a valuable service to their patients. "After all, most doctors with busy practices don't have the time it takes, or the specialized knowledge and skills, to provide thorough genetic counseling," he says.

CMS SOLICITS INPUT ON PRICING OF NEW TEST CODES

The Centers for Medicare and Medicaid Services will hold a public meeting July 18 to solicit input on pricing of 13 new codes for 2017, including three new drug test codes, one molecular pathology code and four genomic sequencing codes. The meeting will take place at CMS headquarters in Baltimore. Three drug tests codes—G0481, G0482 and G0483— are also under reconsideration.

The laboratory public meeting will be held jointly with the annual meeting of the Clinical Diagnostic Laboratory Tests (CDLT) Advisory Panel. CMS will announce preliminary determinations on pricing of the codes by early September, which will be open for comment until early October. Final determinations will be issued in November.

New Test Codes for 2017

Drug Assay

803X1X	Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures, (eg, immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges) includes sample validation when performed, per date of service.
803X2X	Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures, (eg, immunoassay) read by instrument assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.
803X3X	Drug test(s), presumptive, any number of drug classes, qualitative, any number of devices or procedures by instrument chemistry analyzers (eg, utilizing immunoassay), chromatography (eg, GC, HPLC), and mass spec. either with or without chromatography, includes sample validation when performed, per date of service.

Molecular Pathology

813X7X	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis.

Genomic Sequencing Procedures and Other Molecular Multianalyte Assays

814X5X	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, et al.
814X6X	Duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1.
814X3X	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood.
814X2X	Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN.

Multianalyte Assays with Algorithmic Analyses

814X1X	Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score.

Chemistry

844XXX	Testosterone; bioavailable, direct measurement (eg, differential precipitation).

Microbiology

878XXX	Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (eg, Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, herpes simplex virus type 1 and 2, et al), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets.
G0475	HIV antigen/antibody, combination assay, screening.
G0476	Infectious agent detection by nucleic acid (dna or rna); HPV high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) for cervical cancer screening, must be performed in addition to pap test.

LAB STOCKS DOWN 10% YTD

Sixteen lab stocks have declined by an unweighted average of 10% year to date through June 13. In comparison, the S&P 500 Index is up 3.6%. The top-performing lab stocks so far this year are Psychemedics, up 38%, and Enzo Biochem, up 26%. Meanwhile, LabCorp is up 3% and Quest Diagnostics is up 8%.

Company (ticker)	Stock Price 6/13/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$2.04	$3.30	-38%	$33	NA	1.4	1.0
CombiMatrix (CBMX)	2.98	10.95	-73%	4	NA	0.4	0.4
Enzo Biochem (ENZ)	5.69	4.50	26%	262	15.9	2.8	5.1
Exact Sciences (EXAS)	7.04	9.23	-24%	688	NA	13.7	2.4
Foundation Medicine (FMI)	18.53	21.06	-12%	641	NA	6.3	2.7
Genomic Health (GHDX)	25.38	35.20	-28%	838	NA	2.9	6.3
Invitae (NVTA)	7.85	8.21	-4%	252	NA	23.4	2.3
LabCorp (LH)	127.54	123.64	3%	13,060	22.1	1.5	2.6
Myriad Genetics (MYGN)	30.58	43.16	-29%	2,150	20.7	2.9	2.8
NeoGenomics (NEO)	8.13	7.87	3%	627	NA	4.8	3.1
Opko Health (OPK)	9.26	10.05	-8%	5,070	63.4	6.7	2.6
Psychemedics (PMD)	14.01	10.14	38%	76	62.8	2.9	7.0
Quest Diagnostics (DGX)	76.48	71.14	8%	10,820	14.8	1.5	2.4
Rosetta Genomics (ROSG)	1.07	1.23	-13%	22	NA	2.2	1.5
Sonic Healthcare (SHL.AX)	21.39	17.87	20%	8,920	8.9	1.9	2.5
Veracyte (VCYT)	4.97	7.20	-31%	138	NA	2.8	3.4
Unweighted Averages			-10%		29.8	4.9	3.0

Source: Capital IQ

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor Kimberly Scott, Associate Editor